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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,450	03/28/2005	Karsten Eulenberg	052317-1010	8928

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EXAMINER	
KIM, ALEXANDER D	
ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,450	EULENBERG ET AL.	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-15,17-24,28 and 30-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,25-27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: NCBI NP_004888, Notice to Comply.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (mailed on 01/09/2007), Applicants filed a response received on 05/10/2007. Claims 1-36 are pending in this instant Office action.

Election

2. Applicant's election of Group VI (Claims 16, 25-27 and 29) drawn to polypeptide is acknowledged. Because applicant did not distinctly and specifically point out the status of traverse in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

The Group VI reciting "nucleic acid" has a typographical error as pointed out in the response filed on 5/10/2007 and the record stated in the Examiner Initiated Telephone Interview on June 28, 2007. During the telephone interview, Christopher B. Linder and the Examiner agreed that the Group VI should recite "polypeptide" since the Group V is drawn to a "nucleic acid" and also agreed the fact that the Claims will be examined to the extend of the elected subject matter, i.e., method of using said polypeptide.

Claims 1-15, 17-24, 28, 30-36 are withdrawn from consideration as non-elected inventions. Claims 16, 25-27 and 29 will be examined herein.

Priority

3. The instant application is a 371 filing of the International Application No. PCT/EP03/10973 filed on 10/02/2003 as requested in the declaration. The Examiner notes that the requirements of national stage entry of the instant application had been completed (note assigned U.S. filing date) within 30 months of the earliest claimed priority date; the related international application includes both a search report and a preliminary examination report.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to a foreign patent application 02022102.4 (EPO) filed in English on 10/02/2002.

Information Disclosure Statement

4. No information disclosure statement (IDS) has been filed in the instant application.

Compliance with Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to fully comply with the requirements of 37 C.F.R. 1.821 through 1.825; Applicants' attention is directed to the

final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

In the specification, page 29, line 26, the recitation of polypeptides sequence "fwdarw" and "rarw" require appropriate SEQ ID NOs. Appropriate correction is required.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Objections to the Specification

6. The specification is objected to because of the following informalities:

a. The specification is objected to because the title is not descriptive of the claims. A new title is required that is clearly indicative of the invention to which the claims are drawn (see M.P.E.P. § 606.01). The examiner suggests the following new title, for example:

---A method of using Mipp1 polypeptide homolog for making medicaments---

b. The Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the inclusion of the name of the enzyme (multiple inositol polyphosphate phosphatase 1) for Mipp1 and the source species (human and mouse, for example) for completeness.

Claim Objections

7. Claims 27 and 29 are objected to because of the following informalities:

Claims 27 and 29 recite "Use of a", which should have been deleted in the amendment. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 16, 25-27 and 29 is rejected under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 25, 26, 27 (dependent on Claim 22) and 29 (dependent on Claim 1) which recite "a functional fragment" that is a relative term. It is unclear which fragment(s) is encompassed by the scope of claims because the fragment will be different depending on the function. For example, a single amino acid from the protein can be used by a method for making nutritional supplements medicament or pharmaceutical composition, wherein the nutritional deficiency is related to a metabolic disorder. Appropriate clarification is required.

Claim 29 recites the limitation "treatment, alleviation and/or prevention". It is unclear if the claimed method would treat, alleviate and prevent said diseases. The treatment and alleviation of symptom would not be possible when diseases are prevented by the claimed method. Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 16, 25-27 and 29 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a method of using a multiple inositol polyphosphate phosphatase 1 (Mipp1) or related polypeptide of Mipp1 with pharmaceutically acceptable carriers, diluents and/or adjuvant for making a metabolic related syndrome medicament.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (paraphrased from *Enzo Biochemical Inc. v. Gen-Probe Inc.* (CAFC (2002) 63 USPQ2d 1609).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both *Lily* and *Enzo Biochemical* to methods of using products, wherein said products lack adequate written description. While in *University of Rochester v. G.D. Searle & Co.* the methods were held to lack written

description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from *Enzo Biochemical* (see above).

The instant specification teaches a method of using the protein(s) of Table 1 (see page 45 of instant specification) from the source comprising a human, a Drosophila and a mouse. However, the breadth of claim includes a method of using a multiple inositol polyphophate phosphatase 1 (Mipp1), any isoform of said Mipp1, any homolog of said Mipp1, any functional fragment of said Mipp1, any polypeptide variation encoded by a nucleic acid disclosed in Claim 1 and 3 which are related to said Mipp1 and/or any possible modification and changes including but not limited to alteration, deletion, duplication or any fragment(s), from any source, wherein said polypeptide with pharmaceutically acceptable carriers, diluents and/or adjuvants for making any metabolic related syndrome medicament (for any subject or patient) including the disorder disclosed in claims but not limited to said disorder. The prior art by Caffrey et al. (1999, FEBS Letters, vol. 442, page 99-104) teaches a method of using MIPP that is encompassed by the instant claims. The instant specification only discloses a method of measuring a several Mipp1 or related proteins in a human, a mouse and a Drosophila tissues which are potentially useful in forming a medicament. Thus, the prior art and the instant specification do not describe any methods encompassed by the genus claims as described above using a very widely varying polypeptide sufficiently to represent the genus of claimed method. A method of instant specification and prior arts do not

describe a method of using any Mipp1 or any related protein encompassed by the broad claims as described above to represent the correlation between the structure and function of claimed genus method using said any Mipp1. Thus, the instant specification and the prior art cannot describe the structure of a very broad claimed genus and one skilled in the art would not be in possession of the claimed genus by the instant specification.

10. Claims 16, 25-27 and 29 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, because the specification, while being enabling for a method of using the proteins of Table 1 for making a medicament, does not reasonably provide enablement for a method of using any multiple inositol polyphophate phosphatase 1 (Mipp1) from any source, any isoform of said Mipp1, any homolog of said Mipp1, any functional fragment of said Mipp1, any polypeptide variation encoded by a nucleic acid disclosed in Claim 1 and 3 which are related to said Mipp1 and/or any possible modification and changes including but not limited to alteration, deletion, duplication or any fragment(s), from any source, wherein said polypeptide with pharmaceutically acceptable carriers, diluents and/or adjuvants for making any metabolic related syndrome medicament.

The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use of the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The nature of the invention is drawn to a method of using the protein(s) in Table 1 for making a medicament of metabolic disorder. However, the breadth of claims includes a method of using a multiple inositol polyphophate phosphatase 1 (Mipp1), any isoform of said Mipp1, any homolog of said Mipp1, any functional fragment of said Mipp1, any polypeptide variation encoded by a nucleic acid disclosed in Claim 1 and 3 which are related to said Mipp1 and/or any possible modification and changes including

but not limited to alteration, deletion, duplication or any fragment(s), from any source, wherein said polypeptide with pharmaceutically acceptable carriers, diluents and/or adjuvants for making any metabolic related syndrome (for any subject or patient) medicament including the disorder disclosed in claims but not limited to said disorder. The prior art by Caffrey et al. (1999, FEBS Letters, vol. 442, page 99-104) and Applicants teach a method of using a Mipp1 from a human, a mouse or a Drosophila, which can be used to make a medicament for a metabolic disorder. However, applicants disclose no direction or guidance on how to make and use any other said protein encompassed in claims as described above for making any metabolic disorder medicament. Thus, the specification and prior art fail to describe how to make and use the claimed genus method sufficiently. Therefore, it is unpredictable for a method of said Mipp1 or related Mipp1 encompassed by the claims to be used in making any metabolic disorder medicaments. Thus, it is unpredictable for one skilled in the art to make and use a full scope of claimed method that is using any Mipp1 or any Mipp1 variation encompassed by the claims for a very widely varying and very broad metabolic disorder; and such unpredictability makes the level of skill required for one skilled in the art very high to make and use the full scope of claims. For all of the above reason, it would require undue experimentation necessary for a method of using any Mipp1 for any metabolic disorder encompassed by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 16, 25-27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Caffrey et al. (1999, FEBS Letters, vol. 442, page 99-104) evidenced by Elad et al. (1989, Mycophathologia, vol. 105, pages 49-51).

The instant claims are drawn to a method of using a multiple inositol polyphophate phosphatase 1 (Mipp1) or a polypeptide of any Mipp1 variation from any source, wherein said polypeptide with pharmaceutically acceptable carriers, diluents and/or adjuvants for making any metabolic related syndrome medicament.

Caffrey et al. teach a recombinant human Mipp which is also disclosed in the instant Table 1 as NP_004888) (see also NCBI NP_004888 in the attachment). Caffrey et al. teach a method of isolating the human Mipp using the elution buffer of 20 mM Tris-HCl buffer (see bottom of left column, p. 100). Said Tris buffer is known in the prior art to be used for formulating a vaccine for injection into animals as evidenced by Elad et al., middle of left column, page 50. Caffrey et al. also teach a method of using a recombinant human MIPP-like protein C-terminus for raising antibody for detecting a human MIPP like protein (see bottom of left column, p. 100). Thus, the elution of human Mipp by Tris buffer and a method of raising an antibody for the MIPP protein disclosed in Caffrey et al. meets the limitation of a method of using a Mipp1 for making a medicament in pharmaceutically acceptable carriers, diluents and/or adjuvants.

The recitation of "for the treatment of ---" or "for preventing, alleviating or treating ---" said disorder or syndrome are intended use of the product. According to MPEP §2111.02, II, "During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. Also, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." (see MPEP 2112 [R-3]). The intended use for treating, alleviating or treating said syndrome does not results in a structural difference between claimed inventions and the composition comprising a human Mipp by the Caffrey et al. Thus, the method of Caffrey et al. meets all limitation of claims.

Conclusion

12. Claims 16, 25-27 and 29 are rejected for the reasons identified in the numbered sections of the Office Action. Applicants must respond to the objections/rejections in each of the numbered sections in the Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim
June 29, 2007

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER

Notice to Comply	Application No. 10/529,450	Applicant(s) Eulenberg et al.	
	Examiner Alexander Kim	Art Unit 1656	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: See next page.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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7. cont.

In the specification, page 29, line 26, the recitation of polypeptides sequence "fwdarw" and "rarw" require appropriate SEQ ID NOs. Appropriate correction is required.